UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte ANTHONIUS J. SWAAK

Appeal 2007-1628
Application 08/817,704
Technology Center 1600

Decided: September 18, 2007

Before DEMETRA J. MILLS, ERIC GRIMES, and RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal from the final rejection of claims 18, 20, 23-26, 31, and 34-36. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF CASE

The claims are directed to methods of treating rheumatoid arthritis (RA) patients with erythropoietin ("EPO" or "Epo"). "Erythropoietin is a humoral regulator of erythropoiesis, which stimulates the production of erythrocytes [red blood cells]" (Spec. 1: 4-5). "Certain diseases or side-effects of treatments of certain diseases lead to a chronic anaemia which

overcharges the capacity of erythropoietin production, or otherwise cannot be met by the body's own erythropoietin resources" (Spec. 1: 13-16). "In these cases it may be helpful to administer EPO to increase erythrocyte production" (Spec. 1: 24-25).

The Specification describes the treatment of chronic anemia associated with rheumatoid arthritis ("anaemia of chronic disease," or ACD) with EPO (Spec. 2: 31-32). In addition to showing an expected increase in erythrocytes, an overall improvement in the clinical parameters for RA (rheumatoid arthritis) disease scoring activity was observed (Spec. 2: 33 to 3: 17). "The invention thus provides the use of erythropoietin or a substance having erythropoietin-like activity in the preparation of a pharmaceutical for the treatment of chronic inflammations, especially those related to (auto-)immune diseases, in particular RA" (Spec. 3: 3-7).

Claims 18, 20, 23-26, 31, and 34-36 are pending and appealed (Br. 4). Claims 18, 20, 23-26, 31, and 34-36 stand rejected under 35 U.S.C. § 112, first paragraph, as lacking a written description (Answer 4). Claims 18 and 20 are representative and read as follows:

> 18. A method of treating morning stiffness, loss of grip strength, painful joints, or swollen joints in a rheumatoid arthritis patient suffering from morning stiffness, loss of grip strength, painful joints, or swollen joints, consisting of
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> identifying that a patient suffers from morning stiffness, loss of grip strength, painful joints, or swollen joints and
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> administering to the patient that suffers from morning stiffness, loss of grip strength, painful joints, or swollen joints a morning stiffness, loss of grip strength, painful joints, or swollen joints an effective amount of erythropoietin over a treatment period;
>
> identifying that said patient that suffers from morning stiffness, loss of grip strength, painful joints, or swollen joints,

has, after said treatment period in comparison to before said treatment period, a lower level of morning stiffness, loss of grip strength, painful joints, or swollen joints.

20. A method of ameliorating an erythrocyte sedimentation rate or C-reactive protein level in a rheumatoid arthritis patient in need of such amelioration, consisting of identifying that a patient is in need of such amelioration;

administering to the patient an erythrocyte sedimentation rate or C-reactive protein level activity ameliorating effective amount of erythropoietin over a period; and

identifying that the erythrocyte sedimentation rate or C-reactive protein level in said patient has been ameliorated.

DISCUSSION

Under 35 U.S.C. § 112, first paragraph, the Specification must contain a written description of the invention. Thus, when claims are amended during patent prosecution, the claimed invention, in its amended form, must be described in the Specification to comply with § 112, first paragraph. In this appeal, the issue is whether the inventions of claims 18 and 20, which were added by amendment and not part of the Specification as it was originally filed, have a written description in the Specification.

"To fulfill the written description requirement, the patent specification 'must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.' *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). An applicant complies with the written description requirement 'by describing the invention, with all its claimed limitations.' *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997)." *Gentry Gallery v. The Berkline Corp.*, 134 F.3d 1473, 1479, 45 USPQ2d 1498, 1502-1503 (Fed. Cir. 1998).

Thus, the narrower question in this appeal is whether the Specification describes all the limitations recited in claim 18 and 20.

The Examiner has the initial burden of presenting by evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976). In this case, the Examiner contends that "the new limitations [of claims 18 and 20] are found only in a specific example in the context of treating ACD patients (i.e., a specific subset of RA patients) with a specific dosage of Epo, for a specific timeframe, and not in the broad context of the instant claims" (Answer 5). For the reasons that follow, we do not find that the Examiner sustained the burden in establishing that the claims lack written description.

Claim 18

Claim 18 is directed to a method of treating one of four explicitly recited symptoms in a rheumatoid arthritis patient: 1) morning stiffness; 2) loss of grip strength; 3) painful joints; and 4) swollen joints. We find that the Specification describes the invention of claim 18.

Original claims 5 and 6, which were part of the Specification as it was filed, read as follows:

> 5. Use of erythropoietin . . . in the preparation of a pharmaceutical for the treatment of symptoms associated with rheumatoid arthritis.
>
> 6. Use of according to claim 5, wherein the symptoms treated comprise at least one of the group of morning stiffness [1) in claim 18], painful [3) in claim 18] and swollen joints [4) in claim 18], loss of grip strength [2) in claim 18] and pain.

As indicated by the bracketed numbering, claim 6 – which is directed toward the use of erythropoietin for "treatment" of rheumatoid arthritis – provides a written description of all four of the symptoms treated in claim 18.

Claim 6 is not a method claim, as is claim 18. However, Appellant provides evidence that "use" claims would be recognized as a European Patent Office style claim to provide patent protection in Europe for method of treatment claims (Appeal Br. 11-12). He also persuasively argues that a declaration by Dr. Alan J. Howarth shows that persons of ordinary skill in the art would understand from the Specification that the "use" type claims describe methods of treatment (Appeal Br. 11; Declaration of Alan J. Howarth, Ph.D. § 12-15). Although the Examiner is required to review all evidence of patentability (see *In re Sullivan,* ---F.3d---, 2007 WL2433841 (Fed. Cir. 2007)), no mention was made in the Answer of Dr. Howarth's Declaration and the Examiner did not explain why it was insufficient to rebut the rejection.

In addition to the original claims, the Specification describes the use of EPO to improve clinical parameters of disease activity that include morning stiffness ([1) in claim 18]; Spec. 3: 10), tender joints ([3) in claim 18]; Spec. 3: 11), and swollen joints ([4) in claim 18]; Spec., Abstract). In the examples, the Specification describes assessing morning stiffness ([1)]; Spec. 6: 34, 7: 33, and 12, Table IV); loss of grip strength ([2)]; Spec. 6: 33 and 8: 4); and swollen joints ([4)]; Spec. 6: 33-34, 8: 5, and 13, Table V).

In sum, we find that the Specification describes all limitations recited in claim 18. Thus, we reverse the rejection of claim 18, 23, 24, 34, and 36.

The Examiner contends that the only disclosure of "the new limitations" is in a specific example in which RA patients with ACD were treated (Answer 5.)

We do not agree. The Specification states that patients with RA suffering from ACD were first treated with EPO, apparently to ameliorate the symptoms of anemia associated with ACD (Spec. 2: 9-36). However, the Specification states, that in addition to the expected improvement in hemoglobin levels produced by the EPO, "a different unexpected benefit was obtained by the treatment" (Spec. 3: 1-2). This benefit is described as "an overall improvement in the clinical parameters for scoring [RA] disease activity" (Spec. 3: 7-9). As a result, the Specification describes the invention more broadly for treating rheumatoid arthritis, without limiting it to patients with both RA and ACD (Spec. 3: 3-7; 3: 34-35). In other words, treatment of a subset of patients having both RA and ACD led the inventors to the broader discovery of treating RA with EPO.

Claim 20

Claim 20 is directed to a method of administering EPO to ameliorate "an erythrocyte sedimentation rate [ESR] or C-reactive protein [CRP] level in a rheumatoid arthritis patient in need of such amelioration." The Examiner contends that there is no disclosure of ameliorating ESR or CRP levels outside the single example in treating patients with ACD.

We do not agree. ESR and CRP are listed as laboratory parameters for RA disease activity, and the Specification shows that their values were improved by EPO administration (Spec. 7: 20-21 and 11, Table III). While the treatment and consequent improvements in the ESR and CRP values were observed for patients having RA and ACD, the Specification explicitly

describes the use of EPO in RA, without reservation, to improve the clinical parameters for scoring disease activity (Spec. 5: 7-9; original claim 7). As discussed previously, the discovery that EPO ameliorates RA symptoms was made in patients with RA and ACD, but the inventors recognized that it could be used to treated RA more generally and in patients without anemia (Spec. 3: 34-35 and 2: 6-8 (noting that the use of EPO "is not directly related to its erythrocyte stimulating properties")). Thus, we do not find that the Examiner has sustained the burden of showing that claim 20 lacks written description in the Specification as it was originally filed. We reverse the rejection of claims 20, 25, 26, 31, and 35.

CONCLUSION

The Examiner failed to meet the burden of presenting evidence why a person skilled in the art would not recognize in the originally filed Specification a description of the invention defined by the instant claims. Accordingly, the rejection of claims 18, 20, 23-26, 31, and 34-36 as lacking of written description is

REVERSED.

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